REMARKS

Claims 1-37 have been rejected and remain pending. In addition, claims 1, 12, and 32 have been amended to recite that the implantable medical device or non-woven framework is balloon expandable. Claim 9 has been amended to recite that the implantable medical device comprises a stent. Applicants' specification fully supports these amendments. For example, page 6, lines 13-24 disclose that a medical device can be balloon expandable. Thus, no new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 1-37.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 10, 11, and 31 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. With respect to claim 10, the Examiner stated that the specification does not appear to describe attaching the non-woven framework to an exterior surface of a stent. With respect to claim 11, the Examiner stated that it unclear how claim 11 further limits claim 9. With respect to claim 31, the Examiner stated that the specification does not appear to describe fusing the framework to a surface.

Applicants respectfully disagree. Claims 10 and 31 are original claims that form part of Applicants' specification as originally filed. A person having ordinary skill in the art at the time Applicants filed would have understood the subject matter recited in claims 10 and 31. For example, a person having ordinary skill in the art reading Applicants' specification, including original claim 10, would have understood that claim 10 recites a stent having an interior surface and an exterior surface with a non-woven framework attached to at least a portion of the exterior surface. Thus, claims 10 and 31 are clear.

Claim 11 further limits the subject matter of claim 9. Claim 9 recites an implantable medical device that comprises (1) a stent having an interior surface and an exterior surface, (2)

cells, and (3) a non-woven framework. Claim 11 limits claim 9 to an implantable medical device wherein the stent is fabricated from the non-woven framework. Thus, claim 11 is proper.

In light of the above, Applicants respectfully request withdrawal of the rejections of claims 10, 11, and 31 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 102 (e)

The Examiner rejected claims 12, 14, 16-20, 26, and 28 under 35 U.S.C. § 102(e) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069).

Claim 12 has been amended herein to recite that the implantable medical device is balloon expandable. The Vacanti *et al.* reference discloses engineering tissues by (1) subcutaneously implanting a fibrous polymeric matrix for a sufficient time to obtain fibrous tissue or blood vessel ingrowth, and (2) removing the subcutaniously implanted matrix for subsequent implant into a different site. At no point does the Vacanti *et al.* reference disclose an implantable medical device comprising cells and a non-woven framework wherein the implantable medical device is balloon expandable. Thus, the Vacanti *et al.* reference does not anticipate the presently claimed invention.

In light of the above, Applicants respectfully request withdrawal of the rejections of claims 12, 14, 16-20, 26, and 28 under 35 U.S.C. § 102(e).

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected (1) claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069), (2) claims 21-23 under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Ferrara *et al.* (U.S. Patent No. 6,455,283), (3) claims 12, 14-20, and 26-29 under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Healy *et al.* (U.S. Patent No. 5,670,161), (4) claims 21-23 under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Healy *et al.* (U.S. Patent No. 5,670,161) and further in view of Ferrara *et al.* (U.S. Patent No. 6,455,283), and (5) claims 1-7, 9-13, 18-20, and 24-34

under 35 U.S.C. § 103(a) as being unpatentable over Vacanti *et al.* (U.S. Patent No. 6,348,069) in view of Healy *et al.* (U.S. Patent No. 5,670,161), Ducheyne (U.S. Patent No. 5,030,233), and Cottone *et al.* (U.S. Patent No. 5,824,043).

Applicants respectfully disagree. The combinations of references do not render the previously claimed invention obvious. To further prosecution, however, independent claims 1 and 12 have been amended to indicate that the implantable medical device is balloon expandable. In addition, independent claim 32 has been amended to indicate that the non-woven framework is balloon expandable.

A person having ordinary skill in the art reading the cited references would not have been motivated to make or use the presently claimed invention. The Vacanti *et al.* reference discloses engineering tissues by (1) subcutaneously implanting a fibrous polymeric matrix for a sufficient time to obtain fibrous tissue or blood vessel ingrowth, and (2) removing the subcutaniously implanted matrix for subsequent implant into a different site. At no point does the Vacanti *et al.* reference teach or suggest making an implantable medical device comprising cells and a non-woven framework wherein the implantable medical device is implantable and balloon expandable within the vascular system of a mammal. In addition, at no point does the Vacanti *et al.* reference teach or suggest making an implantable medical device comprising cells and a non-woven framework comprising metal fibers wherein the implantable medical device is implantable and balloon expandable within the vascular system of a mammal.

The secondary references fail to correct the deficiencies of the Vacanti *et al.* reference. The Ferrara *et al.* reference discloses nucleic acids encoding vascular endothelial growth factor-E, while the Ducheyne reference discloses porous metal fiber mesh sheets for stabilizing prosthetic devices and repairing defective bone structures. At no point does the Ferrara *et al.* reference or the Ducheyne reference suggest that a person having ordinary skill in the art should modify the materials of the Vacanti *et al.* reference to obtain the presently claimed invention. The Healy *et al.* reference discloses an expandable, biodegradable stent, while the Cottone *et al.* reference discloses a welded stent. At no point does the Healy *et al.* reference or the Cottone *et al.* reference suggest modifying the materials of the Vacanti *et al.* reference to arrive at the

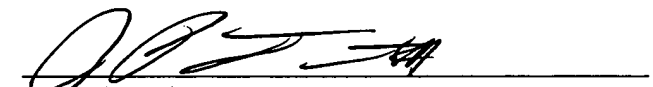
presently claimed invention. In fact, the Healy *et al.* reference and the Cottone *et al.* reference specifically teach that stents can have perforations to permit limited cell ingrowth from the intima after they are implanted. *See, e.g.*, column 4, lines 34-50 of the Healy *et al.* reference and column 6, lines 22-26 of the Cottone *et al.* reference. In addition, at no point do the Healy *et al.* and Cottone *et al.* references suggest making an implantable medical device containing cells, let alone an implantable medical device containing cells and being balloon expandable. Thus, a person having ordinary skill in the art reading the combination of references would not have been motivated to make the presently claimed invention.

CONCLUSION

Applicants submit that claims 1-37 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned attorney at the telephone number below if such will advance prosecution of this application. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: August 11, 2004



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